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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,170	02/27/2004	Alain Fouere	P24980	4885
7055	7590	10/19/2005	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/787,170	FOUERE ET AL.	
	Examiner	Art Unit	
	Patricia M. Bianco	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/04</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Preliminary Amendment*

Applicant filed a preliminary amendment 6/21/03, where portions of the specification were amended, claims 1-16 were amended, and claims 17-23 were added.

Claims 1-23 are currently pending.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following must be shown in the drawings or the limitations must be shown or the feature(s) canceled from the claim(s). No new matter should be entered: **flexible disk** (claim 8); **diablo shape** (claim 11); **instrument with jaws** (claims 16, 17, 22, & 23).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-17 are rejected under 35 U.S.C. 101 because applicant is reciting a process and a structure in the same claim and in a way as to raise question as to whether the claim is directed to a process or to the apparatus, such that it is apparent that the applicant is attempting to cover both in the same claim. Ex parte Lyell, 17 USPQ2d 1548 (BPAI 1990)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11, 15, & 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by MacKeen et al. (4,915,684). MacKeen et al. disclose a method and

apparatus for modulating the flow of lacrimal fluid through a punctum. The apparatus comprises a body that is substantially cylindrical, has an axial bore or duct for the passage of tears, and a disk at one end. The apparatus further has multiple members (58,60) that are seen to be equivalent to applicants pins, since they extend radially outward from the body in a helical formation, are of a constant length, and serve to reinforce & stabilize the apparatus within the punctum. The shape is seen to be in the form of a cone. The apparatus is made of flexible material. The method of inserting the apparatus comprises using an insertion tool that is a dilating rod (i.e. push rod).

Claims 1-4, 7-11, 15, & 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Guena et al. (5,417,651). Guena et al. disclose a punctum plug and probe for inserting the punctum plug. The punctum plug comprises a body that is substantially cylindrical, has an axial hole through the body or duct for the passage of tears, and a disk 5 at one end. The apparatus is made of silicone, which is a flexible material. The apparatus further has a cone 4 that is seen to be equivalent to applicants pins, since extends extend radially outward from the body in a helical formation, are of a constant length, and serve to reinforce & stabilize the apparatus within the punctum. The shape is seen to be in the form of a cone. The method of inserting the apparatus comprises using an insertion tool that is a dilating rod (i.e. push rod).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacKeen et al. ('684) in view of Freeman (3,949,750). MacKeen et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the insert is made of metal or shape memory metal. Freeman discloses a punctum plug that may be made of stainless steel or other inert metal material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of MacKeen to be made of either stainless steel as taught by Freeman or to be made of or Nitinol (shape memory material), since it has been held to be within the general skill of a worker in the art to select a known material

on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416. Freeman discloses to use metal for punctum plugs and it is well known in the art to use shape memory metals such as Nitinol, since both are well received by the body.

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guena et al. ('651) in view of Freeman (3,949,750). Guena et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the insert is made of metal or shape memory metal. Freeman discloses a punctum plug that may be made of stainless steel or other inert metal material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Guena to be made of either stainless steel as taught by Freeman or to be made of or Nitinol (shape memory material), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Freeman discloses to use metal for punctum plugs and it is well known in the art to use shape memory metals such as Nitinol, since both are well received by the body.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacKeen et al. ('684) in view of Herrick (5,163,959). MacKeen et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose

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specifically that the insert is made of a radio-opaque material that is visible with X-rays. Herrick discloses a canalicular implant that may be made of a material that is responsive to X-rays to aid in determining if the implant is properly located within the canaliculi during implantation (col. 13, lines 46-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of MacKeen to be made of a material that is responsive to X-rays as taught by Herrick, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guena et al. ('651) in view of Herrick (5,163,959). Guena et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the insert is made of a radio-opaque material that is visible with X-rays. Herrick discloses a canalicular implant that may be made of a material that is responsive to X-rays to aid in determining if the implant is properly located within the canaliculi during implantation (col. 13, lines 46-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Guena to be made of a material that is responsive to X-rays as taught by Herrick, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.



Claims 16, 17, 22, & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacKeen et al. ('684) in view of Seder et al. (4,959,048). MacKeen et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the tool used to implant the plug includes jaws. Seder et al. discloses using a forceps for insertion of the plug. It would have been an obvious matter of design choice to modify the method of insertion of MacKeen et al. to substitute the forceps as the tool, as taught by Seder et al., since applicant has not disclosed that using a forceps device solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well.

Claims 16, 17, 22, & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guena et al. ('651) in view of Seder et al. (4,959,048). Guena et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the tool used to implant the plug includes jaws. Seder et al. discloses using a forceps for insertion of the plug. It would have been an obvious matter of design choice to modify the method of insertion of Guena et al. to substitute the forceps as the tool, as taught by Seder et al., since applicant has not disclosed that using a forceps device solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent-Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 15<sup>th</sup>, 2005

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**

Patricia M Bianco  
Primary Examiner  
Art Unit 3761